

**REMARKS**

Upon entry of this amendment, claims 1, 2, 13-14, 17-32, 34, 35, 41, 64, 65, 68-80, and 82-86 will be pending in this application. Claims 64-80 and 82-84 were rejoined by the examiner in the Office Action dated October 7, 2008. Applicants have canceled claims 3-12, 15, 16, 33, 36, 37, 42-63, 66, 67, and 81 without prejudice and expressly reserve the right to pursue the subject matter in this or a related application.

Applicants are amending claims 1, 17, 29, 64, 68, 74, 76, 77, 82, 83, and 84 for clarity. Applicants have amended claims 1, 29, 64, and 77 to clarify that the proteolytic cleavage site comprises the amino acid sequence of SEQ ID NO: 1. Applicants have amended claims 29 and 77 to clarify that the vector comprises Factor VII and Factor IX, respectively, and to provide consistency in the language of the claims. Applicants are amending claims 74, 76 and 84 to correct typographical errors. Applicants are amending claims 17, 68 and 83 to provide consistency in the language of the claims. Applicants are amending claim 82 such that a polypeptide is no longer recited, and reserve all rights to pursue the originally claimed subject matter in future examination and/or a divisional or continuation application. The amendments are supported by, *inter alia*, the specification and claims as originally filed.

Claims 85 and 86 are added herein. Exemplary support for the claims is located at paragraph [0039] of the specification and originally filed claims 1 and 7. In rejecting prior versions of claims reciting any proteolytic cleavage site for allegedly failing to meet the written description requirement under 35 U.S.C. § 112 (Office action mailed May 3, 2006, page 4), the examiner stated “The claims are broader than the disclosure of SEQ ID NO: 1, 2, 3, and PACE/furin sites and proteolytic cleavage sites from retroviruses Env and Gag.” Here, applicants are presenting new claims 85 and 86 that recite explicitly a PACE/furin proteolytic cleavage recognition site. Additionally, new claims 85 and 86 are supported by Provisional Application No. 60/191,331, for example, at page 3, in the first paragraph under the heading “PRELIMINARY DATA,” and thus are entitled to the benefit of the provisional application.

No new matter is introduced by the present reply.

### **Claim Objections**

The examiner has objected to claims 81 and 82 for being drawn to a non-elected invention. Without conceding the propriety of the objection and in an effort to advance prosecution of the application, Applicants have canceled claim 81. Without relinquishing any rights to pursue the subject matter of claim 82 in a continuing application, claim 82 is amended to omit reference to a polypeptide. Applicants respectfully request entry of the amendment and withdrawal of the objections.

The examiner has objected to claim 64 for an alleged failure to make clear whether “SEQ ID NO:1 is the sequence for [RKRRKR] or is an example of a sequence containing [RKRRKR].” As a preliminary matter, Applicants respectfully note that the examiner’s recitation of the amino acid sequence “RLRRLR” in this objection on page 3 of the Office Action should read “RKRRKR”, as K is the one letter abbreviation for lysine. Without conceding the propriety of the objection and in an effort to advance prosecution of the application, Applicants have amended claim 64 to clarify that the proteolytic cleavage site comprises the amino acid sequence of SEQ ID NO: 1. Applicants respectfully request entry of the amendment and withdrawal of the objection to claim 64.

### **Rejections based on Scaria, et al. (US 2003/0229036)**

Claims 1, 2, 13-25, 29-32, 34, 35, 41, 64-73, 77-80, and 82-84 are rejected under 35 U.S.C. § 103, as allegedly being obvious over Scaria *et al.*, US. 2003/0229036 (the Scaria publication), Wolf (US 5,795,863), and Miller *et al.* (U.S. 6,924,365). Claims 1, 24, 28, 64, 72, 73, and 76 are rejected under 35 U.S.C. § 103 as allegedly obvious in view of the Scaria publication, the Wolf patent, and the Miller patent for the same reasons as the claims listed above, and in further view of Amalfitano *et al.* (US 6,328,958). Claims 1, 24, 26-27, 64, 72, 74, and 75 are rejected under 35 U.S.C. § 103 as allegedly obvious in view of the Scaria publication, the Wolf patent, and the Miller patent for the same reasons as the claims listed above, and in further view of Kochanek *et al.* (US 5,981,225). Claims 1, 2, 13-23, 29-32, 34, 35, 41, 64-73, 78-80, and 82-84 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-7 of U.S. Patent No. 7,211,558 in view of the Scaria publication.

In short, all of the pending rejections rely on the Scaria publication. The Scaria publication corresponds to U.S. Application No. 10/057,620, filed on October 25, 2001, which claims benefit of Provisional Application No. 60/243,046, filed October 25, 2000 and Provisional Application No. 60/307,492, filed July 24, 2001. The present application, U.S. Application No. 09/816,688, was filed March 22, 2001 and claims the benefit of Provisional Application No. 60/191,331, filed March 22, 2000.

It appears that the Office may be of the view that the claims of the present application and the claims most recently submitted in the patent application corresponding to the Scaria publication (*i.e.*, U.S. Application No. 10/057,620) are directed to at least obvious variants of each other because the present claims have been rejected over the Scaria publication and the claims of the Scaria publication have been rejected over the international patent publication corresponding to the instant patent application, *i.e.* WO 01/70763 A1 (see Office Action dated April 4, 2006, in U.S. Application No. 10/057,620).

Applicants respectfully submit that the rejections lodged by the present Action are incomplete because, although the examiner alleges that the claims pending at the time of the last Office Action would have been obvious in light of a publication (*i.e.*, the Scaria publication) that qualifies as prior art, if at all, under Section 102(e), the Action does not indicate whether the examiner is of the view that an interference should be declared. It is unclear, for example, whether Applicants should submit a Rule 131 affidavit showing that the subject matter of the present claims was invented prior to the priority date of the Scaria publication. According to M.P.E.P. § 706.02(b), “when the claims of the reference U.S. patent or U.S. patent application publication and the application are directed to the same invention or are obvious variants, an affidavit or declaration under 37 CFR 1.131 is not an acceptable method of overcoming the rejection. Under these circumstances, the examiner must determine whether a double patenting rejection or interference is appropriate.”

Applicants further respectfully note that the Scaria application (U.S. Application No. 10/057,620) is awaiting a decision on a Petition for review, filed August 25, 2008, from the Office of Petitions. It is not clear whether the examiner can declare an interference until a decision on the Petition is rendered.

Until Applicants receive additional information from the Office concerning the Scaria publication and corresponding application, Applicants cannot adequately respond to the

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**PATENT**

above rejections. Accordingly, Applicants request that, upon resolution of the status of the Scaria application, the Office indicate whether it intends to declare an interference between the present application and the Scaria application so that Applicants have appropriate notice of the context and form in which its showing, relative to the Scaria application, is to be presented if the present rejections are to be overcome.

Applicants respectfully note, as stated above, that new claims 85 and 86 are entitled to the benefit of Provisional Application No. 60/191,331 such that the Scaria publication does not qualify as prior art as to those claims.

### **Conclusion**

Applicants believe that the foregoing constitutes a complete and full response to the Office Action of record. Accordingly, an early and favorable Action is respectfully requested. Should any issues remain unresolved by the present remarks, the examiner is invited to contact the undersigned at 215.568.3100.

Respectfully submitted,

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